

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231*Sc*

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/063,227 04/20/98 CASAS-BEJAR

J P-7109

QM12/1112

EXAMINER

THOMAS F WOODS  
MEDTRONIC INC  
7000 CENTRAL AVENUE NE  
MINNEAPOLIS MN 55432

THISSELL, J

ART UNIT	PAPER NUMBER
----------	--------------

3762

*9*

DATE MAILED:

11/12/99

Please find below and/or attached an Office communication concerning this application or  
proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. <b>09/063,227</b>	Applicant(s) <b>Casas-Bejar et al.</b>
	Examiner <b>Jeremy Thissell</b>	Group Art Unit <b>3762</b>

Responsive to communication(s) filed on Jul 21, 1999

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claim

Claim(s) 13-25, 27, 29, 33, and 34 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 13-25, 27, 29, 33, and 34 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 4, 8, 9

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 3762

## **DETAILED ACTION**

### ***Election/Restriction***

1. Applicant's election of Group/Invention II, claims 13-25, 27, 29, 33, and 34 in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. As per applicant's request, claims 1-12, 26, 28, 30-32, and 35 have been cancelled.

### ***Drawings***

3. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

### ***Specification***

4. The disclosure is objected to because of the following informalities:

The list of references in the specification on pages 3-5 is not a proper IDS. Any references that were not disclosed on a properly filed IDS were not considered, in particular the non-patent literature for which no copies were supplied. Any references disclosed by applicant on form PTO-

Art Unit: 3762

1449 or cited by the examiner on form PTO-892 will of course be printed on the face of the patent when it issues, thus there is no need for the listing to appear in the specification.

Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 13-22, 24, 25, 27, 29, 33, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chait '555 in view of Fearnott et al '629.

Chait teaches a catheter having an external fitting coupled to the proximal end, and helical coils as claimed. Chait lacks the porous layer with anti-inflammatory agent in it.

Fearnott teaches a catheter (col. 6, line 25) having a polyimide porous layer 20 (col. 9, line 46) with dexamethasone (col. 8, line 66) in it. Fearnott also teaches that the catheter can have heparin embedded in it (col. 8, line 49). Although Fearnott does not teach that the catheter outer layer is made of silicone, Fearnott does teach that part of the catheter can be made of silicone (co. 7, line 9). Since silicone is a material well known to be used in forming catheters, it would have been obvious to form

Art Unit: 3762

the outer porous layer of silicone, especially since Fearnout already teaches that part of the catheter can be made from it.

Fearnout teaches that the device has a layer with the anti-inflammatory steroid in it, and an outer layer 20 with porous structure to control the delivery rate of the drug. Since the drug will at some point be in the porous layer, it is inherent that claims 20-22 are anticipated.

Since Fearnout teaches that the anti-inflammatory agent is carried in a non-porous layer 18, claim 25 is anticipated.

It would have been obvious to one having ordinary skill in the art to form the catheter of Chait with the layered structure of Fearnout, since formation of catheters with layers and with drug-saturated layers is well known in the art of catheters.

The methods claimed in claims 27 and 29 claim only the step of inserting the catheter, which is clearly taught by Chait. The structure claimed in claims 27 and 29 is anticipated by the combination of Chait and Fearnout as discussed supra.

The methods claimed in claims 33 and 34 claim simply that the catheter with the structure as claimed is assembled. The claims do not claim any specifics about the assembly. Clearly, it would have been obvious to one of ordinary skill in the art that the components of Chait must be put together in order to have the structure shown.

7. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chait in view of Fearnout et al as applied to claim 13 above, and further in view of Hendriks et al '151.

Art Unit: 3762

Chait as modified by Fearnout teaches all the claimed subject matter of claim 23 except for the anti-inflammatory agent being covalently bonded to the polymer surface. Hendriks teaches a catheter (col. 4, line 8), having an anti-inflammatory agent (col. 4, lines 23-24), wherein the agent is covalently bonded to the surface of the catheter (col. 4, line 33-35).

It would have been obvious to one of ordinary skill in the art to use the covalent bonding as taught by Hendriks to embed the anti-inflammatory agent of Chait as modified by Fearnout into layer 18 of Fearnout.

#### *References*

The references made of record and not relied upon are structurally similar to applicant's invention, however, do not read on applicant's claims.

The examiner has cited references by Graves and Cahalan (5,925,069 and 5,607,475 respectively) which teach covalent bonding of bioagents to medical devices. See col. 3, line 45 in Graves, and the abstract of Cahalan.

The examiner also wishes to point out that the IDS filed on 1 October, 1998 indicates that there are 6 pages but only 3 are included. Applicant is requested to confirm whether or not there should only be 3 pages. There are no copies of the non-patent literature either. For these references to be considered, copies must be supplied.

Art Unit: 3762

*Contacts*

Any inquiry concerning this communication should be directed to Jeremy Thissell at (703) 305-5261, or to Primary Patent Examiner Ronald Stright (703) 308-2113.

Jeremy Thissell

Patent Examiner

JT

October 28, 1999

  
RONALD STRIGHT  
PRIMARY EXAMINER